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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,295	04/25/2001	Noel Caplice	07039-175001	7824

26191 7590 02/17/2004

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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/843,295

Applicant(s)

CAPLICE ET AL.

Examiner

David M. Naff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 November 2003.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-37 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-37 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

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The amendment of 11/12/03 amended claims 1, 7, 12, 20, 32 and 34. Claims 38 and 39 have been previously canceled.

Claims examined on the merits are 1-37, which are all claims in the application.

5       The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 103***

Claims 1-7, 9-20 and 24-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ducheyne (5,030,233) in view of Davidson  
10   (5,690,670) and Vacanti et al (5,567,612).

The claims are drawn to an implantable medical device comprising a non-woven framework of fibers, which can be metal or polymer fibers, and pores having an average size of at least 40  $\mu$ m, and the framework contains cells and the device is implantable within the vascular  
15   system of a mammal. The framework may also contain an extracellular matrix protein.

Ducheyne disclose a porous metal material for surgical implantation made of metal fibers such as stainless steel or titanium (col 12, lines 45-46), and having a pore size of at least 150  
20   micrometers (col 12, lines 49-50. The material is made by sintering the fibers together (col 7, lines 25-45). As shown by Figure 1, the material is non-woven.

Davidson discloses stents or vascular grafts fabricated from a metal alloy (abstract and col 4, lines 6-40).

5           It would have been obvious to make the metal fiber implant of  
Ducheyne in the form of a stent or vascular graft to obtain the  
expected functions of a stent or vascular graft as disclosed by  
Davidson. It would have been further obvious to provide the metal  
fiber implant of Ducheyne with cells and extracellular matrix protein  
10 as in claim 12 for their expected functions as disclosed by Vacanti et  
al. It would have been additionally obvious to use polymer fibers in  
place of metal fibers as in claim 14 since it would have been apparent  
from Vacanti et al that polymer fibers can provide the same type of  
function as the metal fibers when constructing an implant.

15 *Response to Arguments*

Applicants urge that the claims now require the device to be implantable in the vascular system of a mammal and to contain cells. However, in view of Davidson, it would have been obvious that the implant of Ducheyne can be used as a stent or vascular graft when the device is shaped for this use. Whether the device is used for bone repair or as an implant in a vascular system would depend on its being shaped for insertion in a vascular system, and to shape the device for this use would have been within the skill of the art. Additionally, providing the device with cells and extracellular matrix protein would have been obvious when the functions of these components as disclosed

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by Vacanti et al. The at least 40 micrometer pore size of the claims encompasses the at least 150 micrometer pore size disclosed by Ducheyne.

***Claim Rejections - 35 USC § 103***

5        Claims 8, 21-23 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-7, 9-20 and 24-34 above, and further in view of Ferrara et al (6,455,283 B1).

      The claims require cells that express a polypeptide such as vascular endothelial growth factor.

10        Ferrara et al disclose transforming cells to produce vascular endothelial cell growth factor with a nucleic acid encoding the factor.

      When providing cells in the metal fiber implant of Ducheyne as set forth above, it would have been obvious to use cells encoded to  
15        produce vascular endothelial growth factor as disclosed by Ferrara et al to obtain the expected function of the growth factor to promote the growth of cells contained by the implant and/or at an implant site.

***Response to Arguments***

      As set forth above, the presently claimed combination of claims  
20        1, 12 and 32 would have been obvious. It would have been obvious to use cells in the implant of Ducheyne that produce a vascular endothelial growth factor as disclosed by Ferrara et al since this factor would have been expected to enhance vascular cell growth when the implant is used as an implant in a vascular system as suggested by

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Davidson. The present invention is a combination where the whole is merely the sum of the parts in the absence of an unexpected result.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE**

5 **FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date  
10 of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,  
15 however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

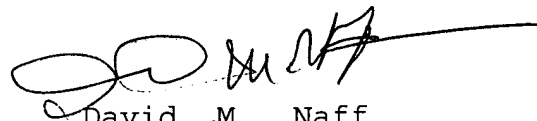
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be  
20 reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

10



David M. Naff  
Primary Examiner  
Art Unit 1651

DMN  
2/9/04